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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,312	08/31/2006	Francis Navarro	403504/WEINSTEIN	8215
23548 7590 10/17/2008 LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960			EXAMINER WACHTEL, EMILY L	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 10/17/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,312	Applicant(s) NAVARRO ET AL.	
	Examiner EMILY WACHTEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2008 has been entered.

Response to Amendment

2. Claims 3 and 16-21 are cancelled. Claims 1-2, 4-15, and 22-25 are pending, new claims 24 and 25 have been entered and claims 1, 7, 22, and 23 entered as amended. The amendments to claims 7 and 23 have overcome the previous objections.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4-5, 7-10, 14-15, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landuyt (U.S. Patent 6,387,076 B1) in view of Bierman (U.S. Patent 7,153, 291 B2).

With regard to claim 1, Landuyt teaches a device for fixing a catheter to a patient, comprising a housing (Figure 1- base plate 1 is taken to be functionally equivalent to the housing), a lid closing the housing (Figure 1 - lid 2, Col. 2 line 27), a base integral to the housing

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and surrounding the housing, for fixation of the housing to skin of the patient (the base is taken to be the underside/lower portion of base plate 1 which is integral to the housing and contains adhesive for securing the base plate to the patient, Col. 3 lines 6-9 see enclosed reference figure 1), wherein the housing comprises first and second chambers which communicate with each other (Figure 1, chamber 1 is taken to be encompassed by opening 12 and enlarged portion 14, Col. 3 lines 34-46, the second chamber is taken to be encompassed by channel 11 specifically locating region 16, Col. 3 lines 43-44 see enclosed reference figure 1), the first chamber includes an opening for passage of the catheter implanted in the patient (Figure 1 -passage 13 Col. 3 lines 38-40) and the lid includes, on an internal face, two pads which penetrate into the second chamber (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3). Landuyt does not teach the second chamber accommodates a supporting base of the catheter and includes a reservoir, the reservoir has a first end connected to the catheter and a second end connected to at least one external tube in fluid communication with the catheter, the supporting base of the catheter includes wings respectively extending from opposite lateral faces of the supporting base, and the lid includes, on an internal face, two pads which penetrate into the second chamber and respectively bear on the wings, holding the supporting base of the catheter against a bottom wall of the second chamber, when the lid is closed. However, Bierman teaches a catheter support base with a reservoir (Fig. 1 catheter support base 12 the reservoir portion taken as 14) with wings (Fig. 1 wings 18) connected to catheter 10 (Fig. 1) and a connection 16 for connecting to an external tube (Fig. 1 Col. 5 lines 34-35). The chamber defined as the second chamber would be capable of accommodating such a winged catheter base and an external tube (see enclosed

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reference figure 1). When closed the pads 35 on the inside surface of the lid of the device of Landuyt would bear down on the base, and effectively the wings, holding it against the bottom of the second chamber. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a catheter with a winged support base in the device of Landuyt as taught by Bierman because increasing the surface area of the catheter base along the bottom of the second chamber would provide greater friction between the elements and provide a more stable securement of the catheter.

With regards to claim 2, Landuyt teaches the housing is flat and has a relatively small height with respect to the base (As seen in Figure 1, housing base 1 has a small height with regards to the overall bottom base), the first chamber and the second chamber are approximately co-planar (the chambers as defined in claim 1 can be seen to be approximately co-planer see enclosed reference figure 1), and two pads (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3), hold the supporting base of the catheter bilaterally with respect to the bottom of the second chamber (the teeth 35 are capable of holding the base of the catheter with respect to the flat bottom, Col. 3 lines 32-36).

With regard to claim 4, Landuyt teaches a catheter retention device substantially as claimed. Landuyt further discloses a wall between the two chambers (see enclosed reference figure) but does not disclose a wall separating the two chambers having oblique lateral faces converging towards the first chamber. However, Bierman teaches that the catheter base support comprises oblique, converging faces (Fig. 5) which are designed to match the shape of the catheter base for better retention. It would have been obvious to a person of ordinary skill in the

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art at the time the invention was made to use a wall passage with oblique converging faces in the device of Landuyt because Bierman teaches using retention means which conform to the catheter supporting base and such would provide a more stable securement of the catheter.

With regard to claim 5, Landuyt teaches an adhesive ring around the circumference of the base plate (Col. 3 lines 9-10). This would effectively encompass a membrane on the bottom of the first chamber, as the bottom of the first chamber is taken to be the portion encompassed in the circumference of the lower portion of the base. This also allows for the passage of the base of the catheter.

With regard to claim 7, Landuyt teaches a catheter retention device substantially as claimed. Landuyt further teaches pads which penetrate the second chamber to secure the catheter within the device and also an additional catheter portin extending into the first chamber (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further penetrate the first chamber with such pads to provide added securement to the device because Landuyt already teaches using pads for catheter securement and further it is within the skill of one in the art to duplicate parts (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

With regard to claim 9, Landuyt teaches the lid and the housing have longitudinal groove to retain a tube (see reference figure 1).

With regard to claim 10, Landuyt teaches the second chamber opens directly

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into the first chamber (Figure 1, see chambers as defined in enclosed figure Reference 1) and includes a hollow part having a shape cooperating (chamber 2 has a hollow portion) with an identical hollow part defined between the two pads (two pads are taken to be outer two teeth 35 of figure 1, the hollow shape of the chamber *cooperates* with the space between these two teeth) of the lid to form, when the lid is closed, a recess which matches the base of the catheter for retaining the base in the housing (the catheter base would be retained within the housing).

With regard to claim 14, Landuyt teaches the lid is articulated to the housing for latching (Fig. 1 hinge 3).

With regard to claims 8 and 15, Landuyt teaches the device being stuck to the skin using adhesive (Col. 3 lines 17-18), taken to be functionally equivalent to the colloid.

With regard to claim 22, see the above rejections to claims 1 and 4.

With regard to claim 23, see the above rejections for claims 1 and 7.

With regard to claim 24, the oblique lateral faces are taken to be the opposing faces generally on either side of a midline through the base (see enclosed reference figure 2). The pads 35 in the device of Landuyt have lateral faces which are oblique to each other (Fig. 2). Further, the pads in the device of Landuyt can be made of an elastomeric material. When the lid is closed such elastomeric pads would conform around the base of the catheter and press against the lateral faces of the base. Further, lateral faces of the pads press against lateral faces of the base as when any surface of the pad comes in contact with the base all parts of the pad effectively are pressing against the base and effectively all faces of the base.

With regard to claim 25, see the above rejection to claim 1 and further the device can hold the supporting base of the catheter bilaterally with respect to the bottom of the second

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chamber (the teeth 35 are capable of holding the base of the catheter bilaterally with respect to the flat bottom, Col. 3 lines 32-36).

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 4 as applied to claim 5 above, and further in view of Kornerup (U.S. Patent 5,685,859).

With regard to claim 6, Landuyt teaches a catheter retention device substantially as claimed. Landuyt does not teach that the membrane comprises slits extending from an edge which delimits the orifice. However, Kornerup teaches a membrane which more closely surrounds the area in which a tube is inserted into the body and shows a slit (Figure 1 slit 2, Col. 5 line 16) which delimits the device. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a membrane with slits in the device of Landuyt because Kornerup teaches such a membrane and this would provide protection around the area in which the catheter was inserted and that in the case where the membrane would more fully cover the aperture and the area in which the tube is inserted in the that slits would be used because this would allow space to accommodate the insertion of the tube and would allow room for tubes of various sizes.

6. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 4 as applied to claim 5 above, and further in view of Bierman (U.S. Patent 6,428,516).

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With regard to claims 11 and 12, Landuyt teaches a catheter retention device substantially as claimed. Landuyt does not teach an adhesive including a sheet of flexible material molded with the housing or two holdfasts in the shape of human ears. However, Beirman teaches flexible anchor pad 32 (Figure 1) for securing the retainer to the patient's skin (Col. 7 lines 9-10). This pad is not disclosed to be molded with the housing however, it would have been obvious to a person of ordinary skill in the art to use a one piece construction and make the parts integral (In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). Further, Beirman shows the pad to be in the shape of two human ears so as to provide greater stability and adhesion to the patient's skin. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to attach the device in Landuyt using an adhesive pad molded to the housing the shape of two human ears as taught by Bierman because it would provide greater stability.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 6 as applied to claim 12 above, and further in view of Wright et al. (US 2004/0167475 A1).

With regard to claim 13, Landuyt teaches a catheter retention device substantially as claimed. Landuyt does not disclose the housing comprising four support holdfasts in the form of human ears. However, Wright et al. teaches a securement device which has a shape that can be taken to be in the shape of four human ears (Page 4 [0045] Figure 11 base 120). And further, that various shapes can be made as desired. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use four ear shaped holdfasts as opposed to

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two in the device of Landuyt because it is within the skill of one in the art to duplicate parts and such has no patentable significance (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)) and further the four holdfasts could provide a support base which better secures the base to the patient as it would provide for increased arrangement possibilities for adhering to the patient's skin, having a greater number of independently movable holdfasts, which could better conform to a variety of locations on the patient.

Response to Arguments

8. Applicant's arguments filed September 3, 2008 have been fully considered but they are not persuasive. Regarding the argument that the substitution of a winged catheter in the device of Landuyt would not be operable, the Examiner respectfully disagrees. The chamber as defined by Landuyt has a depth and width which is capable of accommodating a catheter with protruding wings of a sufficient size. It is not mechanically impossible to incorporate wings into the device of Landuyt. The Applicant has argued that there is no structure described in Landuyt which would apply a compressive force on the wings. The claims recite that the pads bear on the wings and hold the base of the catheter against the bottom wall of the second chamber. The term against simply means to be in contact with. The pads 35 in the device of Landuyt sufficiently bear down on the wings via the body and hold the catheter in contact with the bottom wall of the chamber. Further, the bottom wall would provide a reaction force against the catheter which is pressing down on it due to gravity as well as the pads in the lid of the device of Landuyt. Applicant has stated that the references cannot be used to modify each other because they use different techniques. The Examiner disagrees, both references teach catheter securement devices

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and regardless of the individual techniques being used in the devices it remains obvious to one of ordinary skill in the art to incorporate wings into the device of Landuyt as taught by Bierman to provide the catheter with a more stable securement as stated above. Simply because the winged catheter of Bierman uses adhesive and posts does not mean the device of Landuyt is incapable of accomodating a winged catheter nor does it negate the obviousness reasoning. Adding wings to the catheter of Landuyt still allows the device to retain a catheter against displacement. The Examiner maintains the position that it is obvious to use wings on the catheter of Bierman. Finally, the independent claims as written do not even positively recite the limitation of the catheter, rather the functional reciation of a device *for* fixing a catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767